

108TH CONGRESS
1ST SESSION

H. R. 194

To amend title XVIII of the Social Security Act with respect to reform of payment for drugs and biologicals under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 7, 2003

Mr. STARK introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act with respect to reform of payment for drugs and biologicals under the Medicare Program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Market Ac-
5 quisition Drug Price Act of 2003”.

1 **SEC. 2. REFORM OF PAYMENT FOR DRUGS AND**
 2 **BIOLOGICALS UNDER THE MEDICARE PRO-**
 3 **GRAM.**

4 (a) PAYMENT REFORM.—

5 (1) IN GENERAL.—Section 1842(o) of the So-
 6 cial Security Act (42 U.S.C. 1395u(o)) is amended
 7 to read as follows:

8 “(o) PAYMENT FOR DRUGS AND BIOLOGICALS.—

9 “(1) GENERAL RULE.—If a physician’s, sup-
 10 plier’s, or any other person’s bill or request for pay-
 11 ment for services includes a charge for a drug or bi-
 12 ological for which payment may be made under this
 13 part and the drug or biological is not paid on a cost
 14 or prospective payment basis as otherwise provided
 15 in this part, the amount payable for the drug or bio-
 16 logical shall be based on the following:

17 “(A) MULTI-SOURCE (GENERIC) DRUGS.—

18 In the case of a drug or biological that meets
 19 the requirements for a multi-source drug under
 20 subclauses (I) and (II) of section
 21 1927(k)(7)(A)(i), 105 percent of the volume-
 22 weighted median average acquisition price for
 23 any drug or biological covered under the same
 24 medicare HCPCS code.

25 “(B) SINGLE SOURCE (BRAND) DRUGS AND
 26 BIOLOGICALS.—In the case of a drug or biologi-

1 cal that meets the requirements for a single
2 source drug under section 1927(k)(7)(A)(iv),
3 105 percent of the average acquisition price for
4 the drug or biological.

5 “(C) ACCESS EXCEPTION.—The Secretary
6 may modify the rate otherwise applicable in
7 order to assure access to necessary drugs and
8 biologicals in the case of sole community pro-
9 viders in rural and other areas where the pro-
10 viders are not reasonably able to obtain the
11 drugs and biologicals at the payment rates oth-
12 erwise applicable. Such modification shall not
13 result in a change of more than 15 percent of
14 the rate otherwise applicable.

15 “(D) DATA-RELATED EXCEPTION.—If the
16 Secretary determines that there is insufficient
17 data available with respect to compute an aver-
18 age acquisition price for a drug or biological for
19 a quarter or that, because of a significant
20 change in price from quarter-to-quarter, the
21 available data on the average acquisition price
22 does not accurately reflect the actual, current
23 acquisition cost for the drug or biological, the
24 Secretary may substitute for the quarters in-

1 volved an appropriate payment for the drug or
2 biological for such average acquisition price.

3 “(E) APPLICATION OF NDC CODES.—If the
4 Secretary determines that it is appropriate to
5 provide for payment under this subsection using
6 national drug code (NDC) instead of HCPCS
7 codes, in applying subparagraph (A) the ref-
8 erence to the same HCPCS code shall be
9 deemed a reference to the appropriate national
10 drug codes for those drugs or biologicals that
11 are therapeutically and pharmaceutically equiv-
12 alent and bioequivalent (as defined for purposes
13 of section 1927(k)(7)(A)).

14 “(2) DEFINITION OF AVERAGE ACQUISITION
15 PRICE.—

16 “(A) IN GENERAL.—For purposes of this
17 subsection, the term ‘average acquisition price’
18 means, with respect to a drug or biological and
19 with respect to each dosage form and strength
20 of the drug or biological product (without re-
21 gard to any special packaging, labeling, or iden-
22 tifiers on the dosage form or product or pack-
23 age), the average of all final sales prices
24 charged by the manufacturer of the drug or bio-
25 logical product in the United States, excluding

1 sales exempt from inclusion in the calculation of
2 best price under section 1927(c)(1)(C) (other
3 than under clause (ii)(III) of such section) and
4 excluding sales subject to a rebate under section
5 1927, as reported under paragraph (3).

6 “(B) NET PRICE.—Such average acquisi-
7 tion price shall be calculated net of all of the
8 following (as estimated by the Secretary):

9 “(i) Volume discounts.

10 “(ii) Prompt pay discounts and cash
11 discounts.

12 “(iii) Charge-backs.

13 “(iv) Short-dated product discounts
14 (for spoilage and other factors).

15 “(v) Free goods and services.

16 “(vi) Rebates.

17 “(vii) All other price concessions pro-
18 vided by the drug manufacturer.

19 The Secretary may make subsequent adjust-
20 ments in such average acquisition price to take
21 into account updated information and dif-
22 ferences between the price previously estimated
23 and the actual average acquisition price.

1 “(C) WEIGHTING.—The average of all
2 final sales prices described in subparagraph (A)
3 shall be determined by dividing—

4 “(i) the sum of all final prices charged
5 by the manufacturer (net of the adjust-
6 ments made under subparagraph (B)) for
7 sales in the period involved that are in-
8 cluded in subparagraph (A) for the drug or
9 biological, by

10 “(ii) the total number of units of such
11 sales in the period.

12 “(D) DISTRIBUTION OF REPORTS.—The
13 Secretary shall promptly distribute applicable
14 payment rates under this subsection to carriers
15 and fiscal intermediaries and other contractors
16 that make payment for drugs and biologicals
17 under this section in order to apply a uniform
18 reimbursement rate under this section.

19 “(3) PRICE REPORTING REQUIREMENT.—

20 “(A) IN GENERAL.—As a condition for
21 payment for any drug or biological of a manu-
22 facturer under this subsection, the manufac-
23 turer of the drug or biological shall—

24 “(i) report, on a quarterly basis, to
25 the Secretary (or the Secretary’s designee)

1 the manufacturer's average acquisition
2 price and the information required under
3 subparagraph (C) for all drugs and
4 biologicals of the manufacturer by national
5 drug code (NDC);

6 “(ii) maintain such records (in written
7 or electronic form) regarding such sales
8 and prices for all such drugs and
9 biologicals as may be necessary to audit
10 the information so reported or required to
11 be reported; and

12 “(iii) provide the Secretary with ac-
13 cess to such records in order to permit the
14 Secretary to audit information so reported
15 or required to be reported.

16 “(B) PENALTIES.—The provisions of sec-
17 tion 1927(b)(3)(C) shall apply with respect to
18 the reporting of information under subpara-
19 graph (A) in the same manner as it applies to
20 the reporting of information under section
21 1927(b)(3)(A), except that the reference in
22 clause (i) of such section to \$10,000 is deemed
23 a reference to \$100,000 and any reference to a
24 suspension of an agreement is deemed a ref-
25 erence to a suspension of payment for the drug

1 or biological involved under this part. The Sec-
2 retary shall promptly refer to the Inspector
3 General of the Department of Health and
4 Human Services and, if appropriate, to appro-
5 priate officials in the Department of Justice
6 cases in which the Secretary becomes aware of
7 a false price representation made in the infor-
8 mation submitted under this paragraph.

9 “(C) FORM OF REPORTING.—Information
10 required to be reported under subparagraph
11 (A)(i) shall be reported in a form and manner
12 specified by the Secretary. The information re-
13 quired to be reported shall include the identi-
14 fication of the generic name of the drug or bio-
15 logical and its brand name (if any), the national
16 drug code (NDC) and the HCPCS code as-
17 signed to the drug or biological, the dosage
18 form, strength, volume, and package size in-
19 volved. The information for a quarter shall be
20 submitted not later than 30 days after the end
21 of the quarter. The information shall be accom-
22 panied by a written and signed certification by
23 an officer of the manufacturer attesting to the
24 accuracy of the information reported. Such in-
25 formation shall include updated information on

1 the net price realized (taking into account re-
2 bates and other amounts affecting net price),
3 regardless of the period for which such a rebate
4 or other adjustment in net price might have
5 been earned.

6 “(D) AUDITING.—The Secretary shall
7 audit on a periodic basis information reported
8 or required to be reported under this para-
9 graph. The Secretary may conduct such inde-
10 pendent price gathering activities, such as sur-
11 veys and review of published catalog informa-
12 tion or other transactional information, as may
13 be appropriate to verify the accuracy of the in-
14 formation reported.

15 “(4) DISPENSING FEE.—If payment for a drug
16 or biological is made to a licensed pharmacy ap-
17 proved to dispense drugs or biologicals under this
18 part, the Secretary shall pay a dispensing fee (less
19 the applicable deductible and coinsurance amounts)
20 to the pharmacy. Such a dispensing fee shall be sub-
21 ject to adjustment from year to year based upon
22 changes in the consumer price index over time and
23 may be adjusted as the Secretary determines to be
24 appropriate to reflect differences in the costs of dis-
25 pensing different drugs and biologicals.

1 “(5) PAYMENT REQUIRED ON AN ASSIGNMENT-
2 RELATED BASIS.—

3 “(A) IN GENERAL.—Payment for a charge
4 for any drug or biological for which payment
5 may be made under this part may be made only
6 on an assignment-related basis.

7 “(B) APPLICATION OF ENFORCEMENT
8 PROVISIONS.—The provisions of subsection
9 (b)(18)(B) shall apply to charges for such
10 drugs or biologicals in the same manner as they
11 apply to services furnished by a practitioner de-
12 scribed in subsection (b)(18)(C).”.

13 (2) EFFECTIVE DATE.—Subject to subsection
14 (c)(2), the amendment made by paragraph (1) shall
15 apply to drugs and biologicals furnished on or after
16 January 1, 2004.

17 (b) REVISION IN PRACTICE EXPENSE PAYMENTS.—

18 (1) ADJUSTMENT IN ONCOLOGIST MEDICAL
19 SUPPLY EXPENSES.—In computing the practice ex-
20 pense component of the physician fee schedule under
21 section 1848 of the Social Security Act (42 U.S.C.
22 1395w–4) with respect to payment for services of
23 oncologists, the Secretary of Health and Human
24 Services shall make adjustments to oncologists’ re-
25 ported medical supply expenses in order to ensure

1 that such expenses better reflect the actual supply
2 costs of providing such services.

3 (2) ALLOCATION OF INDIRECT EXPENSES.—In
4 establishing such fee schedule, the Secretary shall
5 change the allocation of indirect expenses in a man-
6 ner so that all services, including services without di-
7 rect physician involvement, are allocated the appro-
8 priate share of indirect expenses.

9 (3) SERVICES WITHOUT DIRECT PHYSICIAN IN-
10 VOLVEMENT.—In establishing such fee schedule, the
11 Secretary shall calculate payments, for those services
12 without direct physician involvement under the basic
13 method, using information on the resources required
14 for each services and, if deemed necessary, shall vali-
15 date the underlying resource-based estimates of di-
16 rect practice expenses required to provide each serv-
17 ice.

18 (4) BUDGET NEUTRAL ADJUSTMENT.—The
19 changes in payment made by this subsection shall
20 not be treated as a change in law or regulation de-
21 scribed in section 1848(f)(2)(D) of the Social Secu-
22 rity Act (42 U.S.C. 1395w-4(f)(2)(D)).

23 (5) EFFECTIVE DATE.—The provisions of this
24 subsection apply to payments for services furnished
25 on or after January 1, 2004.

1 (c) STUDY OF PAYMENTS FOR BLOOD CLOTTING
2 FACTORS AND OTHER BIOLOGICALS.—

3 (1) IN GENERAL.—The Secretary of Health and
4 Human Services shall provide for a study of the ap-
5 propriateness of the medicare payment methodology
6 for blood clotting factors and other biologicals under
7 part B of title XVIII of the Social Security Act. Not
8 later than 9 months after the date of the enactment
9 of this Act, the Secretary shall submit to Congress
10 a report on such study and shall include in such re-
11 port recommendations regarding whether to apply
12 the payment methodology provided under the
13 amendment made by subsection (a)(1) and alter-
14 native recommendations for appropriate dispensing
15 fees.

16 (2) DELAY IN EFFECTIVE DATE.—The amend-
17 ment made by subsection (a)(1) shall not apply to
18 blood clotting factors furnished before the first day
19 of the first calendar year that begins at least 6
20 months after the date the report under paragraph
21 (1) has been submitted to the Congress.

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